

AMENDMENTS TO THE DRAWINGS

Clerical errors have been noted in the labeling of Figure 1. The indication of Polyacetal-GLP (1-6)-His, Polyacetal-Mel (head), and Polyacetal-Mel (head)-Cys has been amended to "Polyacetal-GLP-(1-6)-H, Polyacetal-Mel (head)-QQ, and Polyacetal-Mel(head)-QQ-Cys". Support for the amendment is found in Example 4, paragraph 0058. Both a replacement sheet and a clean version replacement sheet are submitted herewith in the Appendix.

REMARKS

The specification has been amended to show the second occurrence of “Example 6” as “Example 7” and to correct “PEI-1800 (negative control) to PEI-600 (negative control)” in paragraph 0061. Support is found in Figure 6 and within paragraph 0061 which refers to “commercial agent poly(ethylenimine)-600 daltons”.

Claims 2, 4-6, 8, 15, and 18-20 have been cancelled. Claims 1, 3, 7, 9, 12-14, 16, and 21 have been amended. Claims 1, 3, 7, 9-14, 16-17, and 21-27 are now pending in this application. Claims 9-10, 12-14, 16-17, and 21-27 are withdrawn. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Restriction/election

The Examiner’s withdrawal of the restriction between Groups I and II and indication that the Formulae I-IV and SEQ ID NO: 1 are free of the art is gratefully acknowledged. Claims 1-7 and 11 have been examined. Applicants respectfully request rejoinder of claims 9-10, 12-14, 16-17, and 21-27. Claims 9-10, 12-14, 16-17, and 21-27 have been amended to be commensurate in scope with amendments to Group II claims.

Claim objections

Claim 6 is objected to for the recitation of “X” and “Y”.

This objection is moot in view of Applicants’ cancellation of claim 6.

Rejection under 35 U.S.C. § 101

Claim 1 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

This ground of rejection is addressed by amendment of claim 1 to specify that the polynucleotide is “an isolated DNA”.

In view of Applicants’ amendment, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph – written description

Claims 1-7 and 11 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time that the application was filed.

This ground of rejection is addressed in part by amendment taken with Applicants' comments below.

The Examiner states that the claims encompass several classes of polynucleotides. In response, Applicants have amended the claims to specify DNA. As noted by the Examiner, transfection using DNA is shown in the Examples and Figures. One skilled in the art would reasonably expect that any DNA could be transfected by the transfection agents (the polyacetal-peptide) disclosed in the specification. For example, Superfect® and Lipofectamine 2000®, commercially available transfection agents, are used for comparison in the Examples of the specification (see Figures 1 and 5). Both of these reagents transfect DNA generally as evidenced by the product descriptions provided as Attachments A and B. These attachments evidence that reagents similar to the claimed polyacetal-peptides transfect not just specific DNA, but DNA generally. The DNA used in the Examples of the specification is a reporter plasmid used so that the transfection can be tracked and the transfection efficiency quantitated. However, one skilled in the art would recognize that the utility is not limited to the specific reporter genes which were transfected to show the effectiveness of the claimed polyacetal-peptides. One skilled in the art would reasonably expect the transfection agents according to the invention to also be applicable to DNA generally.

In further support of this position, claim 1 has been amended to recite a composition comprising the polyacetal-peptide rather than a complex which includes both a polynucleotide and the polyacetal-peptide transfection agent. The polyacetal-peptide may be used with any DNA.

The Office Action also asserts that there is insufficient written description for polyacetal-peptides as claimed as only one polyacetal-peptide is exemplified in the specification.

Applicants respectfully point out that at least three of the peptides disclosed by Applicants were effective transfection agents as polyacetal-peptides. The Examiner's attention is directed to Figure 1 and Example 4 (paragraph 0058, substitute specification of May 15, 2007)

which discloses successful transfection using polyacetal-peptides where the peptide was GLP (1-6)-His (SEQ ID NO: 8), Mel-head-QQ (SEQ ID NO: 5) or Mel-head-QQ-Cys (SEQ ID NO:6). A further experiment using GLP (1-6) H is described in Figures 5 and 6 and paragraphs 0060-0061 of the substitute specification submitted May 15, 2007. Accordingly, the claims have been amended to recite specifically these three polyacetal peptides. Applicants respectfully submit that there is adequate written description based upon the Examples and Figures discussed above for the amended claims.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1-4 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Kakizawa, (2001, Biomacromolecules, 2, 491).

Claims 1-4 are rejected under 35 U.S.C. § 102 (a) as being anticipated by WO 03/078576A2 (Yu, et al.) as evidenced by Terwilliger, et al. (Biophys. J., 1982, 37, 353).

Both of the above grounds of rejection are addressed by Applicants' claim amendments. Claims 5 and 6 have been incorporated into claim 1.

In view of Applicants' amendments, reconsideration and withdrawal of the above grounds of rejection is respectfully requested.

Double patenting

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending application No. 10/946,383.

This ground of rejection is addressed by incorporation of claims 5 and 6 into claim 1.

In view of Applicants' amendment, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this

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application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee (Entry in **BOLD** is the present application).

| Serial Number | Title | Filed |
|-------------------|---|--------------------|
| 10/341,059 | SOLID SURFACE FOR BIOMOLECULE DELIVERY AND HIGH-THROUGHPUT ASSAY | 13-Jan-2003 |
| 10/789,589 | COMPOSITIONS AND METHODS FOR BIODEGRADABLE POLYMER-PEPTIDE MEDIATED TRANSFECTION | 27-Feb-2004 |
| 10/800,934 | METHODS FOR EXTENDING AMORPHOUS PHOTOREFRACTIVE MATERIAL LIFETIMES | 15-Mar-2004 |
| 10/876,322 | REVERSE SYNTHETIC METHODS FOR MAKING ORGANIC NON-LINEAR OPTICAL MATERIALS | 24-Jun-2004 |
| 10/884,530 | PHOTOCLEAVABLE DNA TRANSFER AGENT | 02-Jul-2004 |
| 10/946,383 | BIODEGRADABLE POLYACETALS FOR IN VIVO POLYNUCLEOTIDE DELIVERY | 21-Sep-2004 |
| 10/954,756 | IMAGE CORRECTION DEVICE | 30-Sep-2004 |
| 10/980,079 | MICROSCOPE SYSTEM AND METHODS FOR INTRACELLULAR STUDIES | 03-Nov-2004 |
| 11/126,878 | BIODEGRADABLE POLYACETALS ANDMETHODS | 10-May-2005 |
| 11/134,820 | HYDROPHILIC POLYMERS WITH PENDANT FUNCTIONAL GROUPS AND METHOD THEREOF | 19-May-2005 |
| 11/216,986 | BIODEGRADABLE CATIONIC POLYMERS | 31-Aug-2005 |
| 11/219,145 | TRANSEPITHELIAL DELIVERY OF PEPTIDES WITH INCRETIN HORMONE ACTIVITIES | 02-Sep-2005 |
| 11/251,956 | INTRACELLULAR PEPTIDE DELIVERY | 17-Oct-2005 |

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| 11/255,735 | (METH)ACRYLATE POLYMER AND NON-LINEAR OPTICAL DEVICE MATERIAL COMPOSITION | 21-Oct-2005 |
| 11/286,243 | VECTOR FOR TRANSFECTION OF EUKARYOTIC CELLS | 23-Nov-2005 |
| 11/303,082 | SOLID SURFACE WITH IMMOBILIZED DEGRADABLE CATIONIC POLYMER FOR TRANSFECTING EUKARYOTIC CELLS | 14-Dec-2005 |
| 11/359,811 | POLYMER COATING OF CELLS | 22-Feb-2006 |
| 11/360,161 | PHOTOREFRACTIVE COMPOSITION | 23-Feb-2006 |
| 11/364,596 | CONTROLLABLY DEGRADABLE POLYMERIC BIOMOLECULE OR DRUG CARRIER AND METHOD OF SYNTHESIZING SAID CARRIER | 27-Feb-2006 |
| 11/525,482 | PEPTIDE NUCLEIC ACID BASED GUANIDINIUM COMPOUNDS | 21-Sep-2006 |
| 11/525,512 | MULTI-VALENT GUANIDINIUM COMPOUNDS FOR ENHANCING MOLECULAR TRANSLOCATION ACROSS CELLULAR MEMBRANES AND EPITHELIAL TISSUES | 21-Sep-2006 |
| 11/526,224 | GUANIDINIUM DELIVERY CARRIERS | 22-Sep-2006 |
| 11/526,927 | SOLID SURFACE FOR BIOMOLECULE DELIVERY AND HIGH-THROUGHPUT ASSAY | 26-Sep-2006 |
| 11/527,134 | SOLID SURFACE FOR BIOMOLECULE DELIVERY AND HIGH-THROUGHPUT ASSAY | 26-Sep-2006 |
| 11/566,141 | POLYGLUTAMATE-AMINO ACID CONJUGATES AND METHODS | 01-Dec-2006 |
| 11/613,895 | METHOD FOR PRODUCING CARBON NANOTUBES, METHOD FOR PRODUCING LIQUID DISPERSION THEREOF AND OPTICAL PRODUCT | 20-Dec-2006 |
| 11/615,831 | TRANSPARENT ELECTRICALLY-CONDUCTIVE HARD-COATED SUBSTRATE AND METHOD FOR PRODUCING THE SAME | 22-Dec-2006 |
| 11/695,365 | BIODEGRADABLE CATIONIC POLYMERS | 02-Apr-2007 |
| 11/747,624 | LIGHT EMITTING DEVICES AND COMPOSITIONS | 11-May-2007 |
| 11/781,508 | NON-LINEAR OPTICAL DEVICE WITH LONG GRATING PERSISTENCY | 23-Jul-2007 |
| 11/781,633 | NON-LINEAR OPTICAL DEVICE SENSITIVE TO GREEN LASER | 23-Jul-2007 |

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the

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Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By:

Che S. Chereskin

Che Swyden Chereskin, Ph.D.
Registration No. 41,466
Agent of Record
Customer No. 20,995
(949) 721-6385

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